REMARKS

Claims 1-49 are pending in the application. The Examiner has withdrawn claims 2-7, 10, 11, 13-14, 18-19, 22-25, 28, 29, 31-32, and 34-49 pursuant to a restriction/election of species requirement. Applicants request reconsideration and allowance of this application in view of the following remarks.

Election/Restriction and Claim Objections/Pending Claims

Claims 42 and 43 are objected to because, although having been withdrawn from consideration by the Examiner, the previous amended claim sheet still referred to them as "original." The presently filed set of claims now refers to those claims as "withdrawn."

Regarding the rest of the claims the Examiner has withdrawn, claims 3, 10, 13, 19, 28, 31, and 32 should not have been withdrawn from consideration, as those claims also read on the assembly shown in Figure 5 (the elected species). In this regard, Applicants note that the drug container shown in the assembly of Figure 5 is actually the same as the drug container shown by itself in Figure 4. (Note the use of the same reference numerals to refer to the drug container and its components between the two figures.) Accordingly, portions of the relevant disclosure are in the specific context of describing Figure 4, not Figure 5. Because the drug container is the same in both Figures, however, that disclosure is germane to Figure 5, too. Therefore, Applicants request favorable consideration of the above-listed claims in this application as well.

Drawing Objection

The drawings are objected to because, according to the Examiner, Figure 5 does not show that the second luer-lock connector directly connects to the first luer-lock connector. Rather, according to the Examiner, Figure 5 shows that the second luer-lock connects to intermediary tubing, such that none of the claims reads on Figure 5.

Applicants submit that this issue arose as a result of the drawing change that was entered in response to the first office action, and that the drawing was actually correct as filed. In

particular, in the previous office action, Figure 5 was objected to because it seemed to show reference numerals 310 and 313 pointing to the same item. Therefore, in response to that office action, reference numeral 310 was moved to point to a different item – namely, the collar at the end of the inlet port extending from the fluid container.

Upon further review, it appears that the objection in the first office action was incorrect, and therefore that the drawing amendment should not have been filed. In particular, closer inspection shows that the lead line from reference numeral 310 in the original drawing actually crosses through the luer-lock 313 that is part of the medicine container cap to touch the luer-lock component that is at the end of the branch of the Y-shaped spike. (See the attached, blown-up portion of the original Figure 5.) Accordingly, Applicants respectfully request that the previously filed amended drawing sheet be disregarded and that originally filed Figure 5 be returned to status as the correct version of Figure 5. That reversion should obviate the new objection to the Figures.

Claim Rejection

Claims 1, 8, 9, 12, 15-17, 20-21, 26, 27, 30, and 33 are rejected under 35 U.S.C. § 103 based on Vaillancourt, U.S. 5,897,526, in view of Karrasch, U.S. 5,279,605, and Post et al., U.S. 5,492,531. Applicants respectfully traverse the rejection and request that it be withdrawn.

Vallaincourt describes a system in which fluid from an infusion bag (10) is mixed with a drug from a vial (25). The fluid from the infusion bag (10) is led via a first line (12) to a Y-site connector (18) and the drug from the vial (25) is lad via a second line (20) to said Y-site connector (18). The fluid from the infusion bag (10) is mixed with the drug from the vial (25) as it flaws out of the Y-site connector (18), i.e. outside the infusion bag, contrary to the present invention where a drug is mixed with a fluid inside the fluid container itself. Dl further describes (in col. 9, lines 60-63) that a clamp (22) is used in the line under the drip chamber (13) to prevent fluid from flowing into the infusion bag, contrary to the present invention where a fluid is actually fed into an infusion bag.

Vaillancourt also describes a rubber disc (element 75 in figure 19) which, contrary to the inventive fluid barrier that is hygienically contained inside a conduit, has to be disinfected before fluid transfer can take place.

Furthermore, Vaillancourt describes an embodiment (that is shown in figures 1, 6, 9 and 13) in which a reservoir bag (23) is filled with fluid from an infusion bag (10) and the fluid from the reservoir bag (23) is used to dilute a solid drug in a vial. This embodiment differs from the present invention in that two fluids are not mixed inside a fluid container but a fluid is mixed with a solid substance (see col. 8, lines 29-36).

Karrasch discloses an infusion system comprising a Y-shaped Luer connector (18) that is connected to a patient and to first (14) and second (20) tubing segments. Fluid from an infusion bag (16) is fed to the patient via the first tubing segment (14) and fluid from the patient is drained via the second tubing segment (20) (see col. 3, lines 15-22). Even though a Luer- connector is used in the disclosed system, it is used in a totally different way than in the present invention. Furthermore, the fluid inside the infusion bag (16) is not mixed with another fluid before it is fed to a patient.

Post describes an infusion system in which fluid from an infusion bag (12) is mixed with a viscous paste-like medical substance from a flexible tube (26). Said fluid and viscous paste-like medical substance are mixed outside the infusion bag (12). A one-way check valve (16) is arranged at the discharge port of the infusion bag (12) to prevent fluid from flowing into the infusion bag (see col. 3, lines 46-49), contrary to the present invention where one actually wants a fluid to flow into the infusion bag.

Post also describes a threaded connector (86) that is screwed onto the tube (26). The connector (66) contains a membrane (92) that has to be perforated in order to get the medical substance out of the tube (26). While the connector (86) is being screwed onto the tube (26) the membrane (92) is perforated with a piercing member (78) that is arranged on the connector (86)

(see col. 4, lines 51-63), contrary to the present invention where a rupturable fluid barrier such as a brittle polymer member, is ruptured after corresponding Luer-connectors (110-113/111-213 of figure l) have been connected.

The examiner asserts the device that is described in Vaillancourt discloses all of the technical features of claim 1 apart from the features that the connector is a Luer-connector and that the fluid barrier is rupturable. The examiner assers that Karrasch (in figure 1, element 18 and col. 4, lines 16-20) shows that Luer-connectors are used in an infusion system and that Post shows (in figure 2, element 92 and col. 4, lines 51-55) a piercable membrane. The examiner therefore considers that it would be obvious for a skilled person to combine the teachings of the three references and arrive at a fluid transfer system according to the present invention.

The infusion bag that is described in Vaillancourt does not however comprise an inlet for the introduction of fluid from a vial. The only fluid that enters Vallaincourt's infusion bag is air (via valve 17). Neither Vaillancourt nor any of the other cited documents describes a system in which a fluid is introduced into a fluid container, such as an infusion bag, whereby the contents of the fluid container are mixed with said introduced fluid inside the fluid container. A skilled person wanting to improve a fluid transfer system where a fluid is to be mixed with the contents of a fluid container inside the fluid container itself would not therefore read any of the cited documents.

Even if a skilled person were to combine the contents of the cited documents, he/she would not arrive at a construction according to the present invention comprising two Luer-connectors which make quick and safe connection between an infusion bag and a vial possible. Vaillancourt and Post do not mention a Luer-connector at all. In Karrasch, even though a Y-shaped Luer-connector (18) is mentioned, it is used to connect two tubing segments (14, 20) to a patient, i.e. it is used in a completely different application.

Piercable membranes that prevent a fluid or medical substance from flowing out of a fluid container until the membranes are pierced are well known. However it is not known to arrange a

fluid barrier, such as a brittle polymer member that is arranged to be ruptured by an external force, inside the inlet to a fluid container and/or the outlet of a drug container, whereby said inlet comprises a Luer-connector for connection to a corresponding Luer-connector on said outlet to transfer fluid from the drug container to the fluid container.

Applicants therefore submit that claim 1 is new since none of the cited documents recite all of the features of claim 1. Furthermore, it would not have been obvious for a skilled person to arrive at the inventive system, even if he/she combined the teachings of the various references. Accordingly, Applicants traverse the rejection and request that it be withdrawn.

In view of the foregoing, Applicants submit that all non-withdrawn claims are in condition for allowance, and timely notice to that effect is respectfully requested.

The undersigned representative requests any extension of time that may be deemed necessary to further the prosecution of this application.

In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner should directly contact the undersigned by phone to further the discussion.

Respectfully submitted,

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